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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,922	02/09/2004	Kristopher Henry Vietmeier	S63.2B-11269-US01	8838

490 7590 07/10/2006

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

COZART, JERMIE E

ART UNIT	PAPER NUMBER
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3726

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/774,922

Applicant(s)

VIETMEIER, KRISTOPHER
HENRY

Examiner

Jermie Cozart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/06, 6/2/06, 6/14/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 36 and 37 are objected to because of the following informalities: In **claim 36**, *line 3*, "directed" is objected to because it is the incorrect word used, therefore it is suggested to change "directed" to - -direct- -; In **claim 37**, *line 3*, "directed" is objected to because it is the incorrect word used, therefore it is suggested to change "directed" to - -direct- -;. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mackiewicz et al. (US 2005/0060025 A1).

Mackiewicz discloses a precursor (34) for an implantable medical device (i.e. stent) having at least a portion of the precursor (34) made of a shape memory material (i.e. nitinol), the shape memory material having a receptacle (38) for receiving a marker (36) therein, the shape memory material having an austenitic and a martensitic phase. The receptacle (38) has a shape and is enlarged while the shape memory material is in the martensitic phase, and a marker (36) is inserted in the receptacle (38) while the shape memory material is in the martensitic phase, and thereafter the precursor is transformed to the austenitic phase. The precursor is a medical device one example

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being a stent precursor which encompasses a stent-graft precursor. The precursor having a plurality of receptacles (38) for receiving a plurality of markers (36).

Mackiewicz discloses heat being applied to the plurality of receptacles (38) prior to transforming the precursor to the austenitic phase. The precursor is post-processed to form an implantable device (i.e. stent or stent-graft) suitable for implantation in the body, wherein the post-processing includes the step of polishing the precursor. The stent has a first end and a second end, wherein the receptacle (38) is positioned (figs. 6-7) at the first end of the stent. The marker (36) is radiopaque. The marker (36) does not comprise material (paragraph 0035) in common with the shape memory material of the implantable medical device and wherein the marker (36) is in direct contact with the shape memory material of the implantable device after the precursor is transformed to the austenitic phase. *See paragraphs [0021]-[0054], and figures 1-7 for further clarification.*

Mackiewicz, however, does not disclose the following: the shape of the receptacle being maintained during the enlarging step; the receptacle being positioned between the first end of the stent and the second end of the stent; the implantable medical device being formed prior to the receptacle being enlarged; the implantable medical device and the receptacle being made from different materials; the shape memory material being polymeric; or the shape of the receptacle being substantially circular.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to maintain the shape of the receptacle during the enlarging step, to position the receptacle between the

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first end and second end of the stent, to form the implantable medical device prior to the receptacle being enlarged, to make the implantable medical device and the receptacle from different materials, to make the shape memory material polymeric, and to make the shape of the receptacle substantially circular because Applicant has not disclosed that maintaining the shape of the receptacle during the enlarging step, positioning the receptacle between the first end and second end of the stent, forming the implantable medical device prior to the receptacle being enlarged, making the implantable medical device and the receptacle from different materials, making the shape memory material polymeric, or forming the shape of the receptacle as substantially circular provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with that which is taught by Mackiewicz because the markers are effectively held within the receptacles of the implantable device and the implantable device is easily locatable when deployed.

Therefore, it would have been an obvious matter of design choice to modify Mackiewicz to obtain the invention as specified in claim 1-39.

Response to Arguments

4. Applicant's arguments with respect to claims 1-35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jermie Cozart whose telephone number is 571-272-4528. The examiner can normally be reached on Monday-Thursday, 7:30 am - 6:00 pm.

7. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Bryant can be reached on 571-272-4526. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JERMIE E. COZART
PRIMARY EXAMINER

July 6, 2006